Patent Application
Attorney Docket No. PC10818AATJ

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Leah E. Appel, et al.

APPLICATION NO.: 09/745,095

FILING DATE: December 20, 2000

TITLE: Hydrogel-Driven Drug Dosage Form

Examiner: S. Gollamudi
Group Art Unit: 1616

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this 29th day of March 2002

By

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

This is in response to the Office Action, a Restriction Requirement, mailed on October 29, 2001 in the above-identified application, the term for response having been extended four (4) months by including the appropriate fee and petition herewith.

REMARKS

Applicants herein elect, with traverse, the invention of Group II, Claims 2, 7-9, 12-32, 44-45, 49-53, 56-81, 88-97, 101, 103-108, 118-122, 124, and 130-131, drawn to a controlled dosage form, classified in class 424, subclass 472.

The Examiner further required an election of species for prosecution on the merits. The Examiner stated that drug, swelling agent, drug-entraining agent, tableting aid, cellulosic polymer, fluidizing agent, solubilizer, pore former, and concentration enhancing agent were generic. Applicants elect the following

A drug - - sildenafil citrate
B swelling agent - - sodium croscarmellose
C drug-entraining agent - - polyethylene oxide
D tableting aid - - microcrystalline cellulose
E cellulosic polymer - - cellulose acetate
F fluidizing agent - - xylitol
G solubilizer - - citric acid
H pore former - - polyethylene glycol
I concentration-enhancing polymer - - hydroxypropylmethyl cellulose acetate succinate (HPMCAS).

The Restriction Requirement is traversed on the basis that it is excessive. It is noted that six out of seven of the restriction groups, i.e., all of the Groups except Group IV,